FEB 2 2 2001

K001631

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

AJW Technology Consultants, Inc.
962 Allegro Ln.
Apollo Beach, FL 33572

Phone: 813-645-2855
Fax: 813-645-2856

Contact Person: Art Ward

Date of Summary: May 1, 2000

Trade Name: CORTEX METAMAX

Classification Name: Calculator, Pulmonary Function Data
21 CFR Section 868.1880

Predicate Device: K963373 K4 Cosmed S.R.L.

Device Description/ Comparison:

The CORTEX METAMAX metabolic test system is a portable device, which can monitor parameters via telemetry, data storage or on line during laboratory testing, actual or simulated conditions. The device is comparable to the Cosmed K4 system.

The device is software driven. Adequate software testing with respect to the new IEC 601-1-4 has been conducted on the device. The device is battery or electrically operated.

Intended Use:

The CORTEX METAMAX pulmonary function mobile test system is a device which monitors the cardio-respiratory functions during stress testing, rehabilitation, sports medicine and other related activities. The METAMAX system allows the use of telemetry for the monitoring of metabolic perimeters. The METAMAX system is intended to use with adults and children over the age of 14 years.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2001

Cortex Biophysik GmbH
c/o Mr. Arthur J. Ward
AJW Technology Consultants, Inc.
962 Allegro Lane
Apollo Beach, FL 33572

Re: K001631
MetaMax® Models II and 3B, and MetaSoft
Regulatory Class: II (two)
Product Code: 73 BZC
Dated: November 24, 2000
Received: November 30, 2000

Dear Mr. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001631

Device Name: CORTEX METAMAX MetabolicTest System

Indications For Use:

The CORTEX METAMAX pulmonary function mobile test system is a device which monitors the cardio-respiratory functions during stress testing, rehabilitation, sports medicine and other related activities. The METAMAX system allows the use of telemetry for the monitoring of metabolic parameters. The METAMAX system is intended to use with adults and children over the age of 14 years.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001631

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)